K080241

NOV 2 8 2008

510(k) Summary

Contact: Mr. Justin Eggleton
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Device Trade Name: DSS™ Stabilization System – Rigid Coupler

Manufacturer: Paradigm Spine, LLC
505 Park Ave. 14th Floor
New York, NY 10022
212.583.9700

Common Name: Pedicle screw spinal system

Classification: 21 CFR §888.3070

Class: III

Product Code: NKB, MNH, MNI

Indications For Use:
The DSS™ Stabilization System – Rigid Coupler is intended for noncervical pedicle fixation from the T4 to S1 vertebrae in skeletally mature patients to help provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion. The DSS™ Stabilization System – Rigid Coupler is intended to be used with autograft and/or allograft.

Device Description:
The DSS™ Stabilization System is comprised of a variety of pedicle screws and Rigid Couplers that act as longitudinal spacers. This device is intended to be used with bone graft to provide immobilization and stabilization of a spinal segment as an adjunct to fusion.

The DSS™ Stabilization System consists of:

- DSS™ pedicle screw sets
- DSS™ Rigid Couplers

The DSS™ Stabilization System is fabricated from wrought Ti-6Al-4V (ISO 5832-3 and ASTM F136).

Predicate Device(s):
The DSS™ Stabilization System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used, including, but not limited to:

1. DePuy MOSS Miami (K962628)
2. Biomet Synergy VLS Open (K973836)
3. Synthes Pangea (K052123)
4. Zimmer Silhouette (K993067)

Performance Standards:
Testing performed indicates the DSS™ Stabilization System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Paradigm Spine, LLC
c/o Musculoskeletal Clinical
Regulatory Advisors, LLC
Mr. Justin Eggleton
1331 H Street Northwest, 12th Floor
Washington, DC 20005

NOV 2 8 2008

Re: K080241
Trade/Device Name: DSS™ Stabilization System - Rigid
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: NQP,
Dated: October 27, 2008
Received: October 29, 2008

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.

Furthermore, the indication for use:

> The DSS™ Stabilization System – Rigid is intended as a single-level system for noncervical pedicle fixation from the T4 to S1 vertebrae in skeletally mature patients to help provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion. The DSS™ Stabilization System – Rigid is intended to be used with autograft and/or allograft.

must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Suzette Y. Mahmoud M.D.

Donna-Bea Tillman, Ph.D., M.P.A. FOR DR. TILLMAN
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080241

Device Name: DSS™ Stabilization System – Rigid

The DSS™ Stabilization System – Rigid is intended as a single-level system for noncervical pedicle fixation from the T4 to S1 vertebrae in skeletally mature patients to help provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion. The DSS™ Stabilization System – Rigid is intended to be used with autograft and/or allograft.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080241